



US009220897B2

(12) **United States Patent**
Perryman et al.

(10) **Patent No.:** **US 9,220,897 B2**
(45) **Date of Patent:** **Dec. 29, 2015**

(54) **IMPLANTABLE LEAD**

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(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

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(21) Appl. No.: **14/045,764**

International Preliminary Report on Patentability in International
Application No. PCT/US2012/050633, issued Feb. 18, 2014, 7
pages.

(22) Filed: **Oct. 3, 2013**

(Continued)

(65) **Prior Publication Data**

US 2014/0031837 A1 Jan. 30, 2014

Related U.S. Application Data

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(63) Continuation of application No.
PCT/US2012/003220, filed on Apr. 4, 2012.

(57) **ABSTRACT**

(60) Provisional application No. 61/471,496, filed on Apr.
4, 2011.

(51) **Int. Cl.**

A61N 1/00 (2006.01)
A61B 18/04 (2006.01)
A61N 1/36 (2006.01)
A61N 1/378 (2006.01)
A61N 1/05 (2006.01)
A61N 1/372 (2006.01)

(52) **U.S. Cl.**

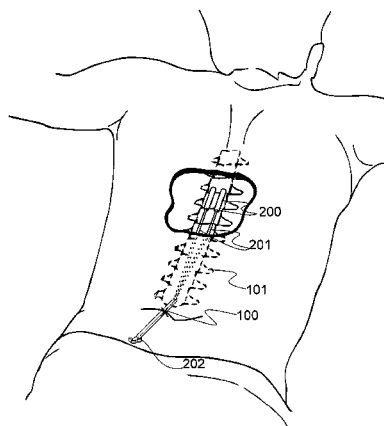
CPC **A61N 1/36071** (2013.01); **A61N 1/0551**
(2013.01); **A61N 1/3787** (2013.01); **A61N**
1/37229 (2013.01); **A61N 1/36182** (2013.01)

(58) **Field of Classification Search**

USPC 607/116; 606/33
See application file for complete search history.

An implantable wireless lead includes an enclosure, the enclosure housing: one or more electrodes configured to apply one or more electrical pulses to a neural tissue; a first antenna configured to: receive, from a second antenna and through electrical radiative coupling, an input signal containing electrical energy, the second antenna being physically separate from the implantable neural stimulator lead; one or more circuits electrically connected to the first antenna, the circuits configured to: create the one or more electrical pulses suitable for stimulation of the neural tissue using the electrical energy contained in the input signal; and supply the one or more electrical pulses to the one or more electrodes, wherein the enclosure is shaped and arranged for delivery into a subject's body through an introducer or a needle.

28 Claims, 15 Drawing Sheets



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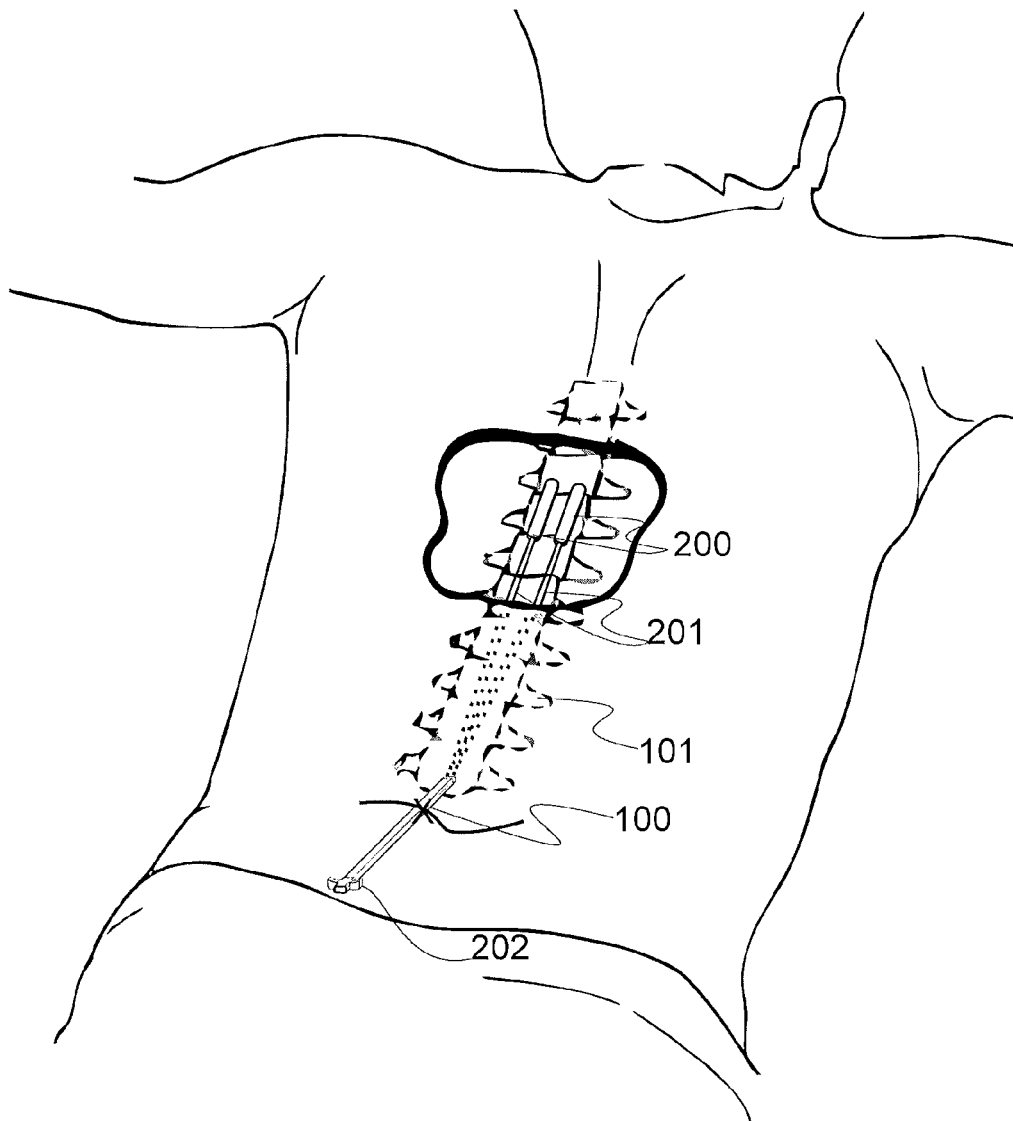


FIG. 1

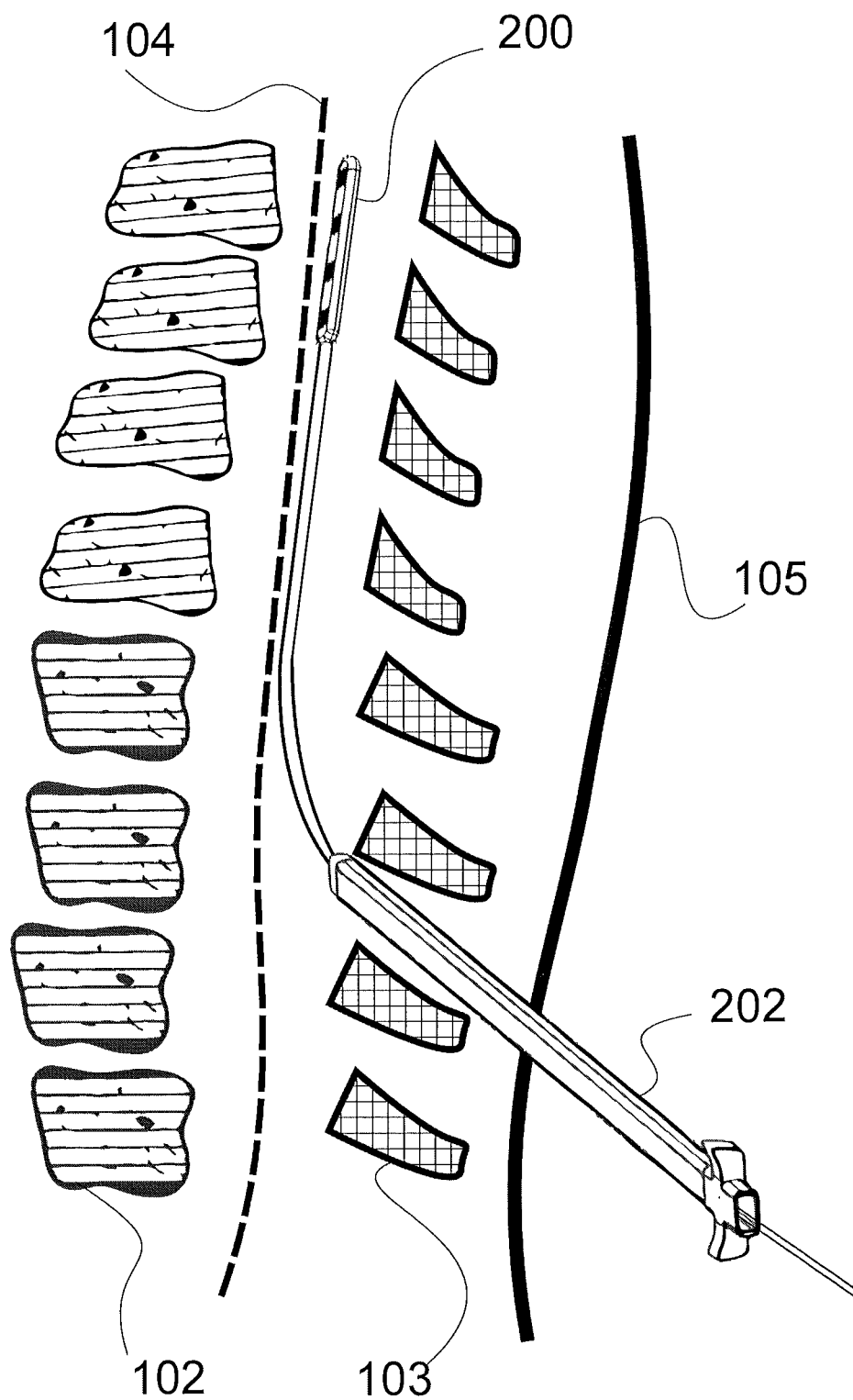


FIG. 2

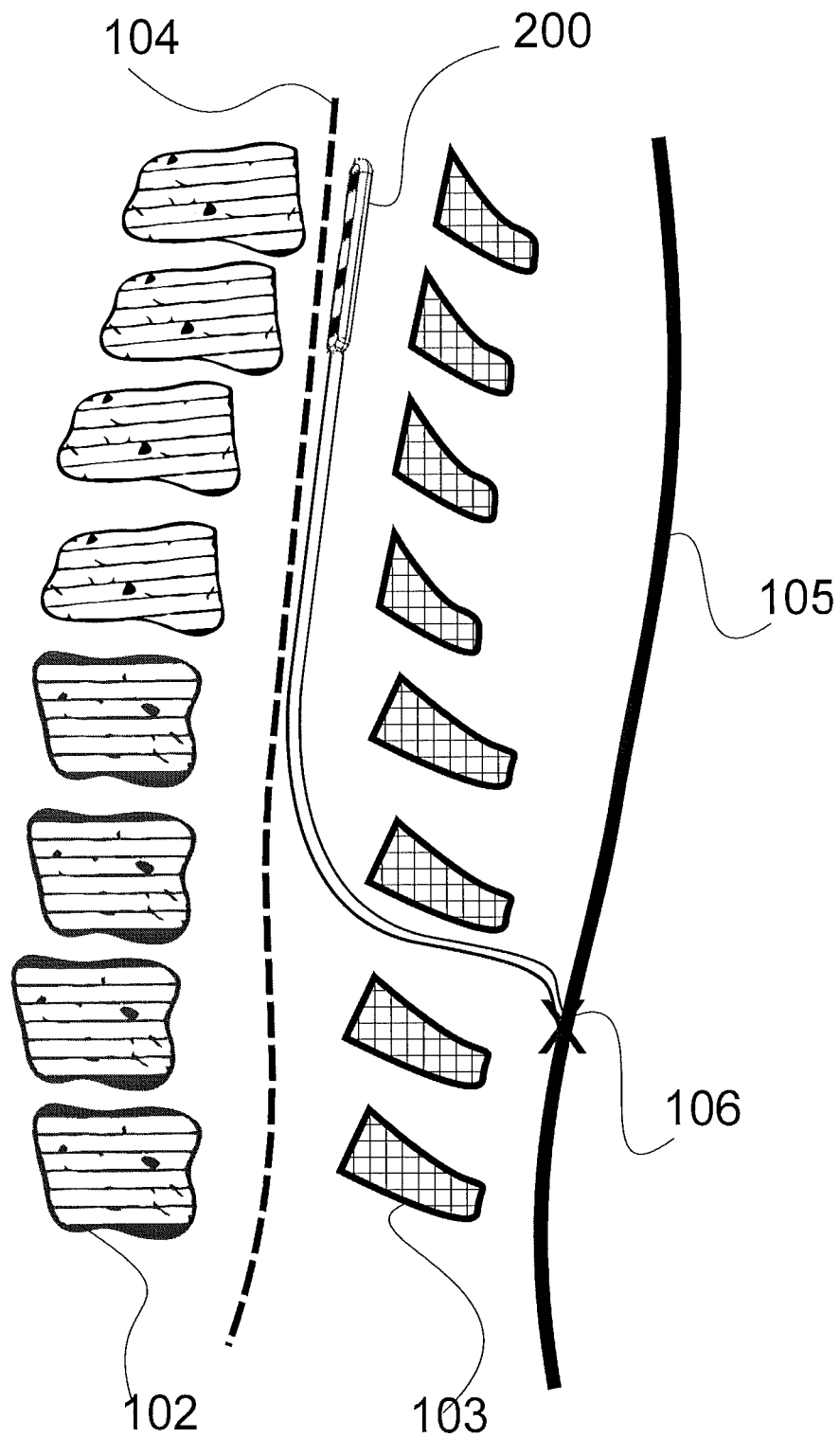


FIG. 3

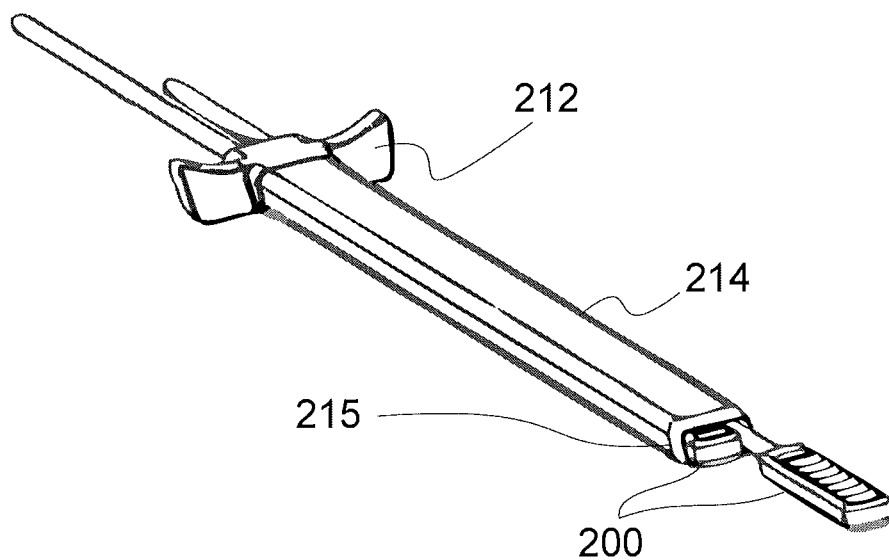


FIG. 4A

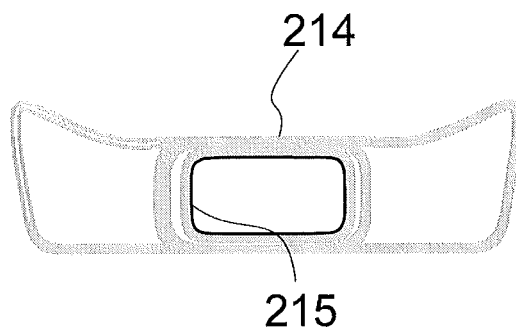


FIG. 4B

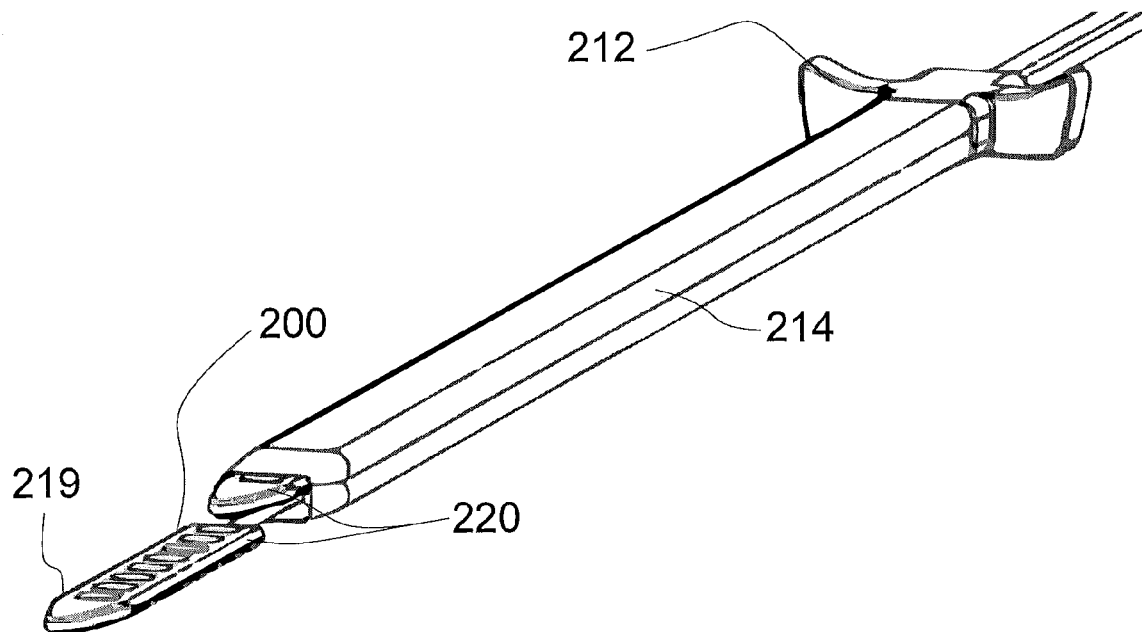


FIG. 5A

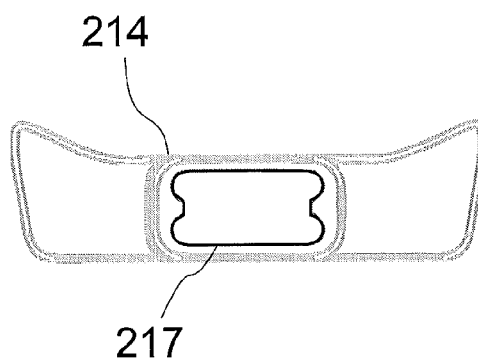


FIG. 5B

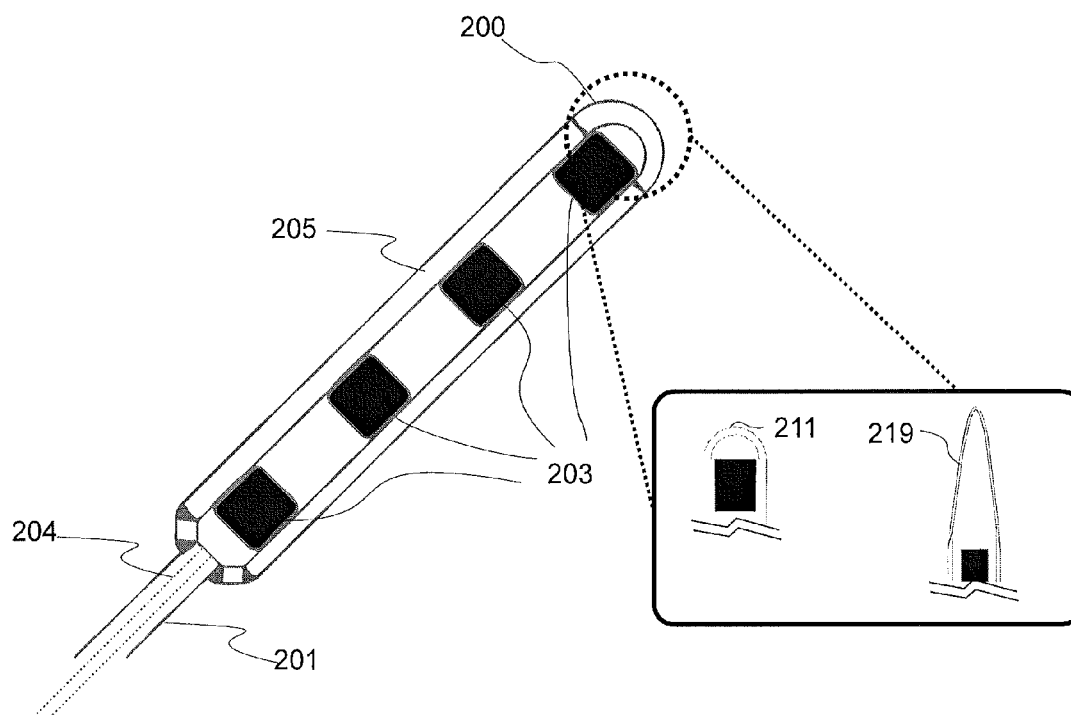


FIG. 6A

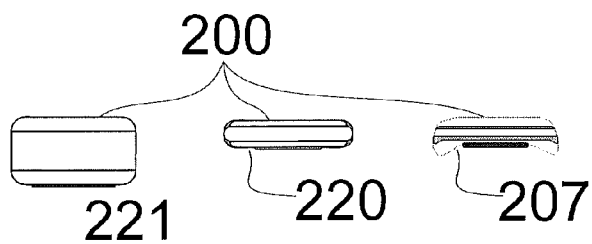


FIG. 6B

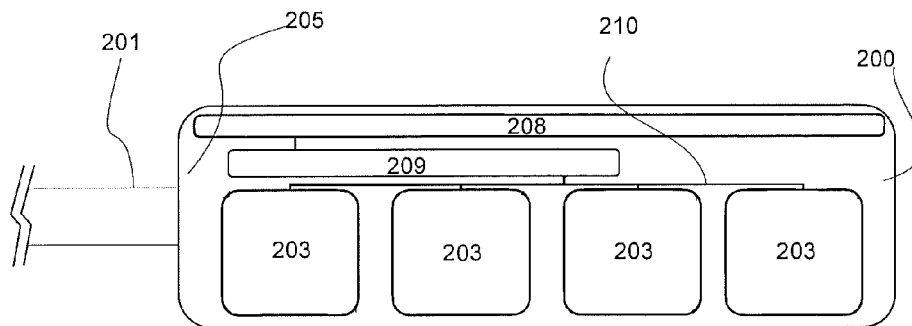


FIG. 7A

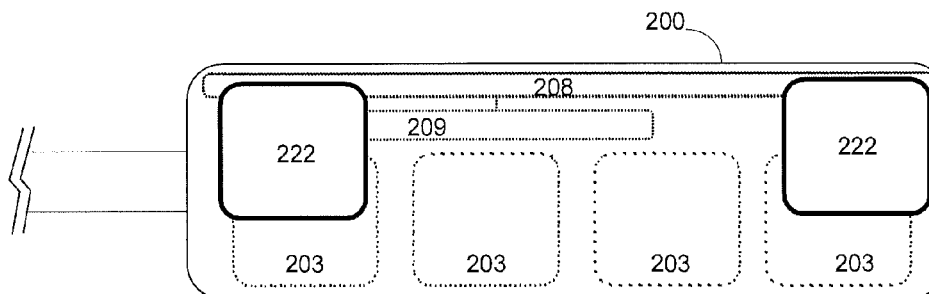


FIG. 7B

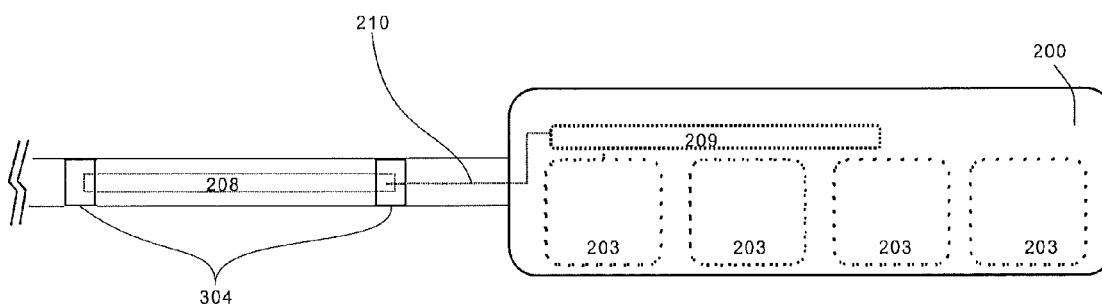


FIG. 7C

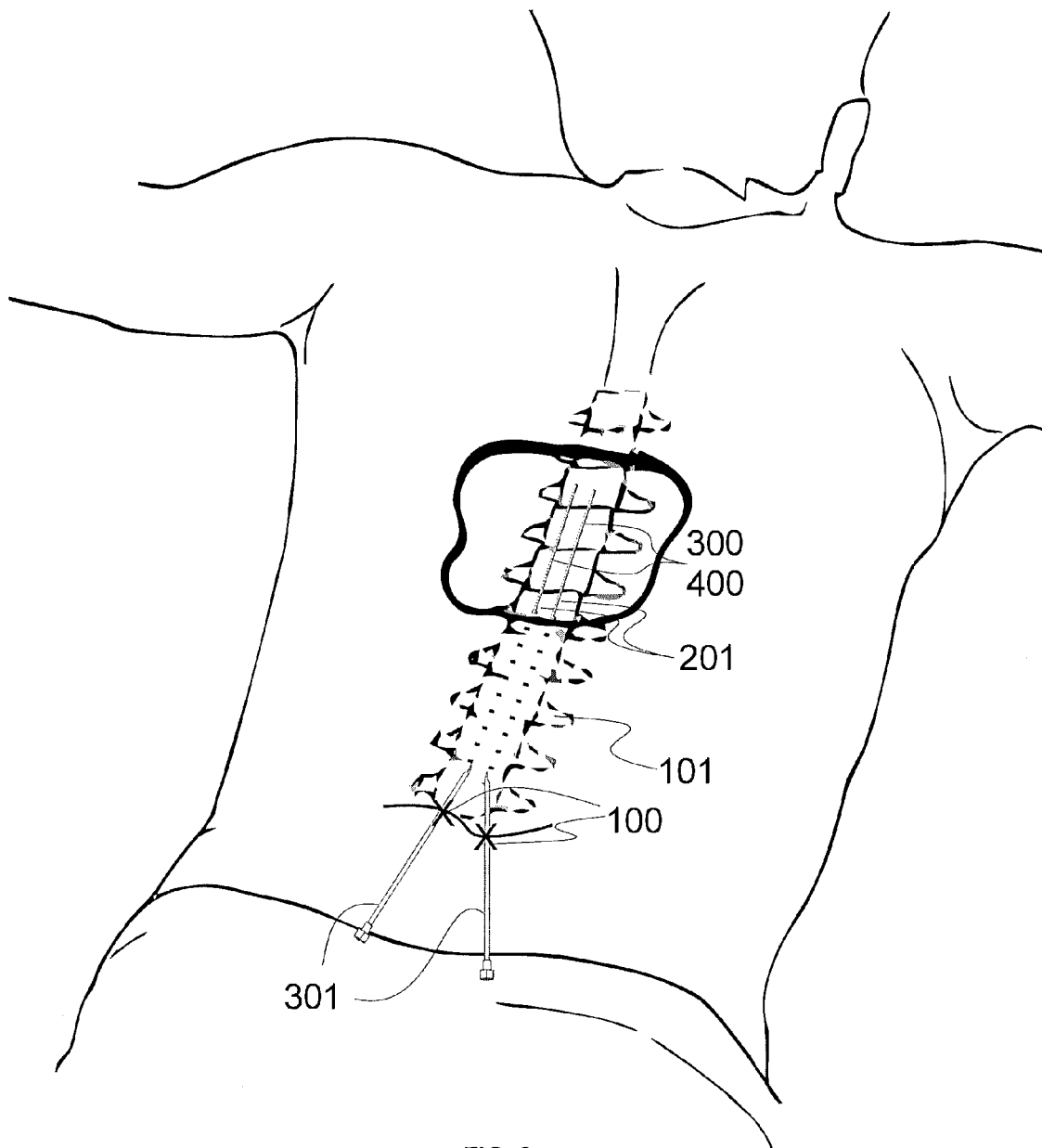


FIG. 8

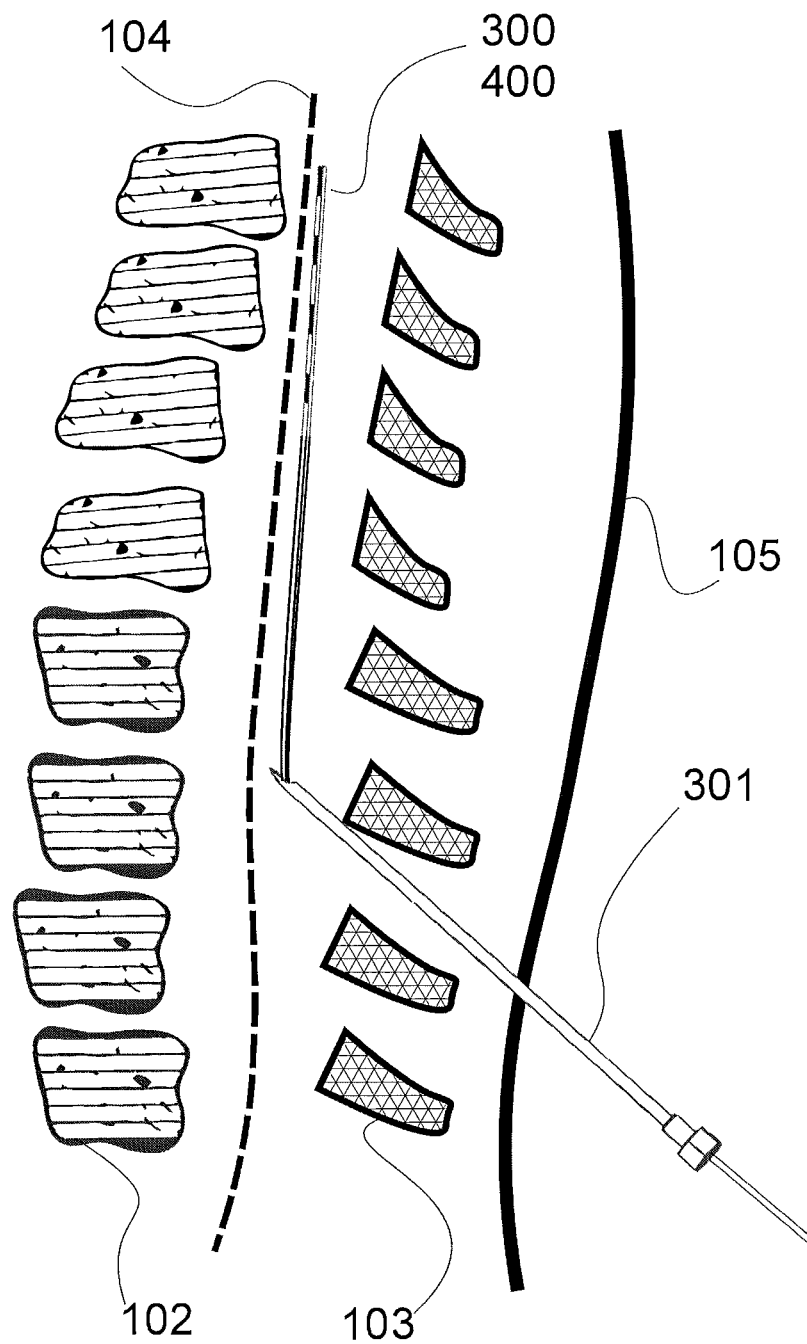


FIG. 9

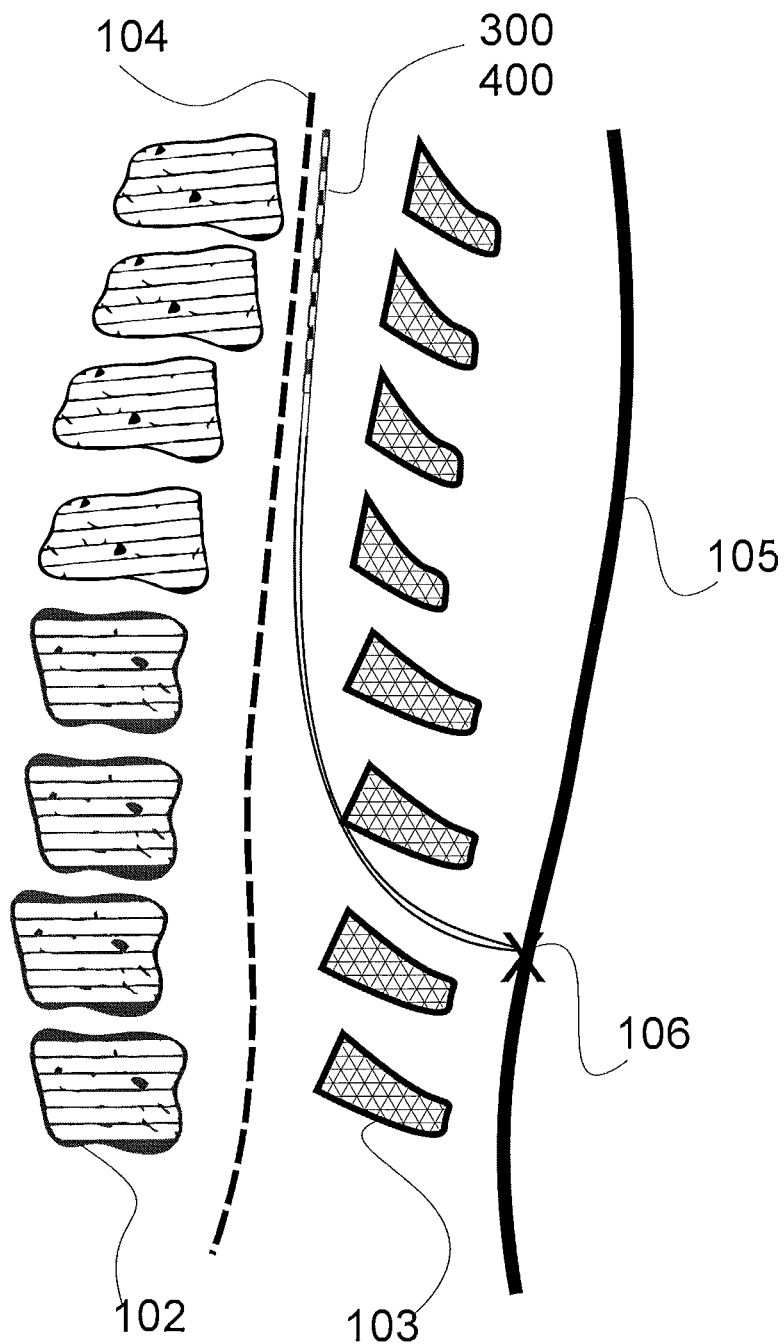
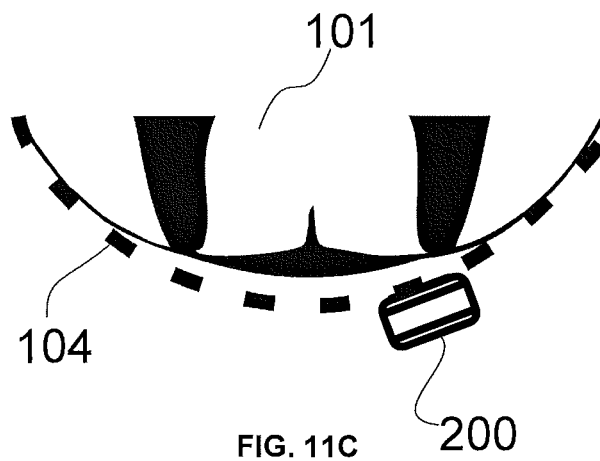
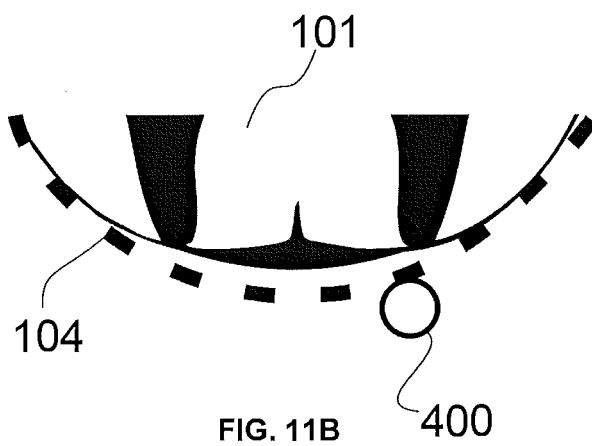
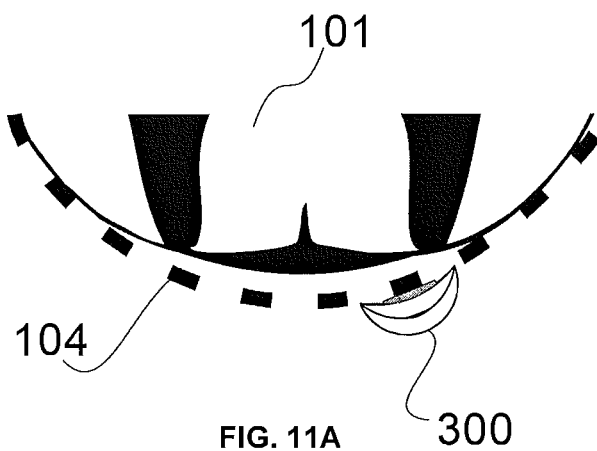


FIG. 10



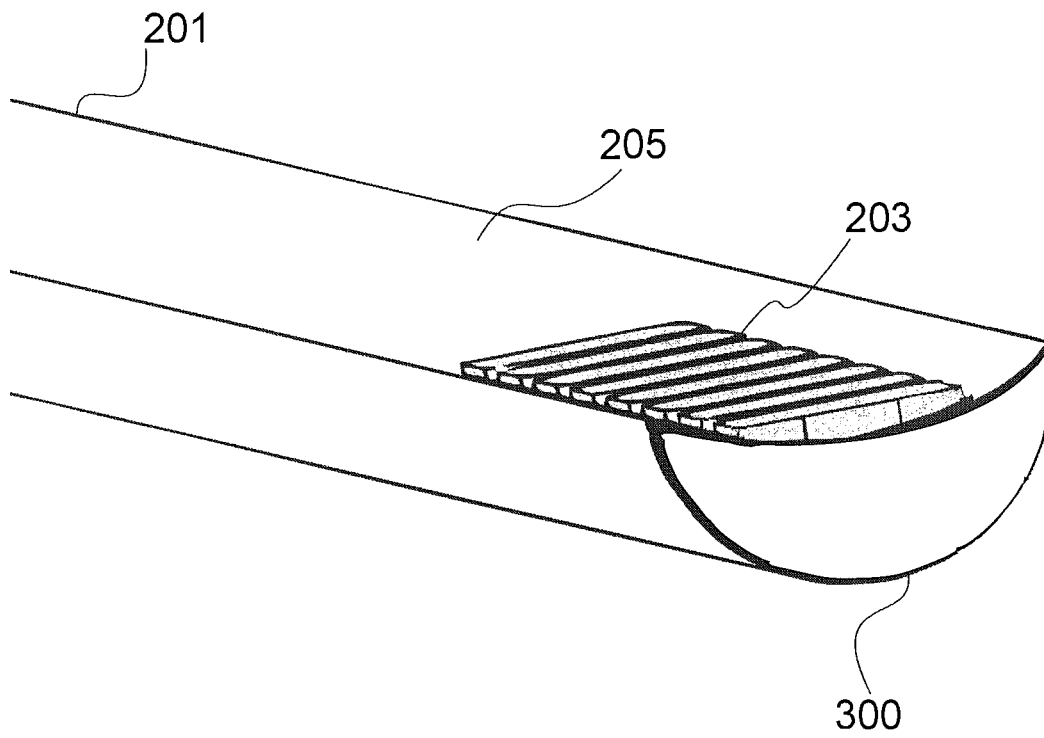


FIG. 12A

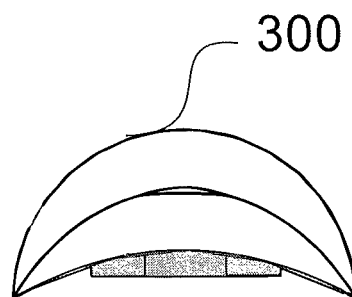


FIG. 12B

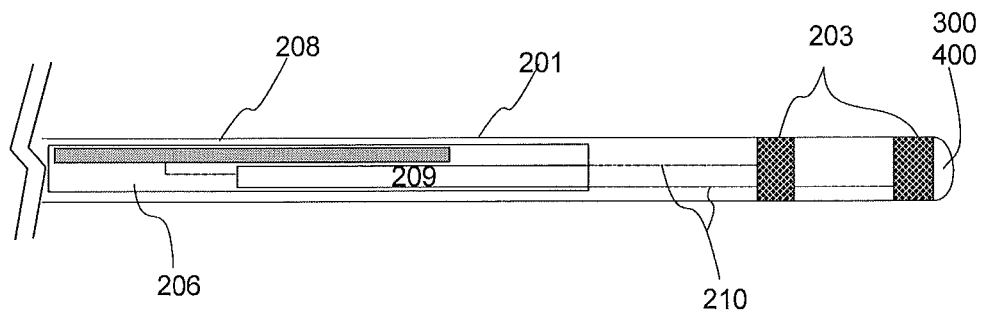


FIG. 13A

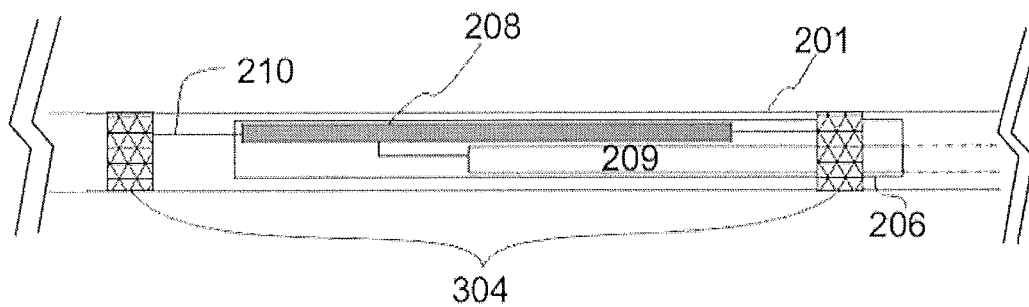


FIG. 13B

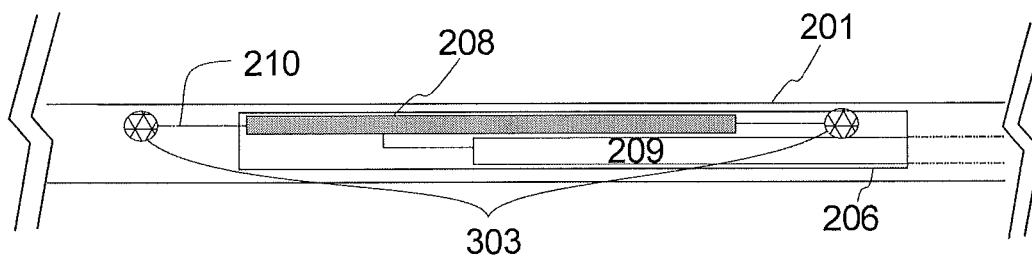


FIG. 13C

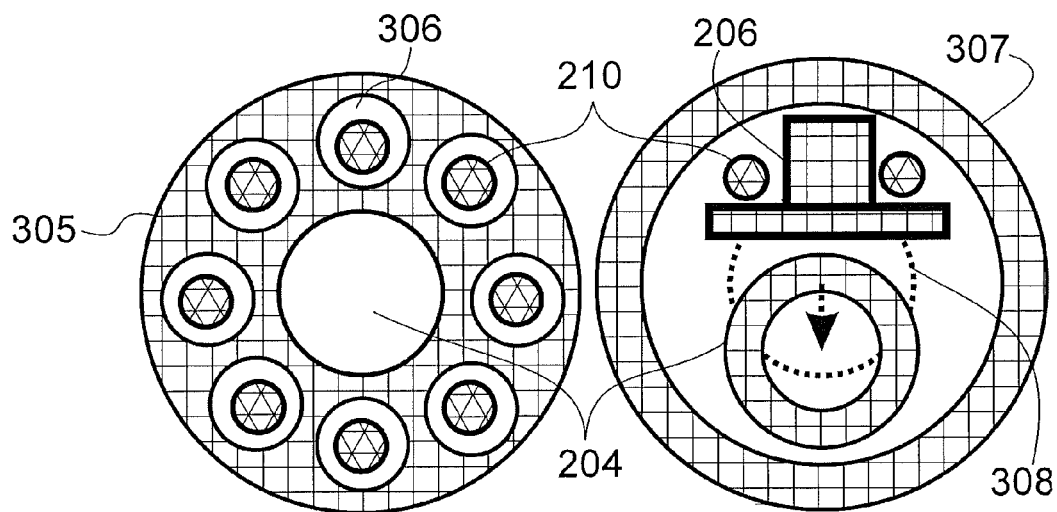


FIG. 14A

FIG. 14B

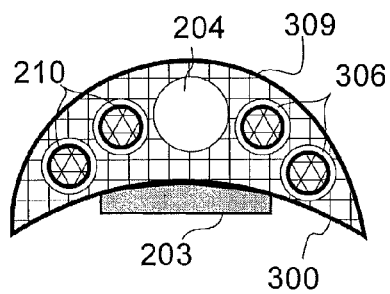


FIG. 14C

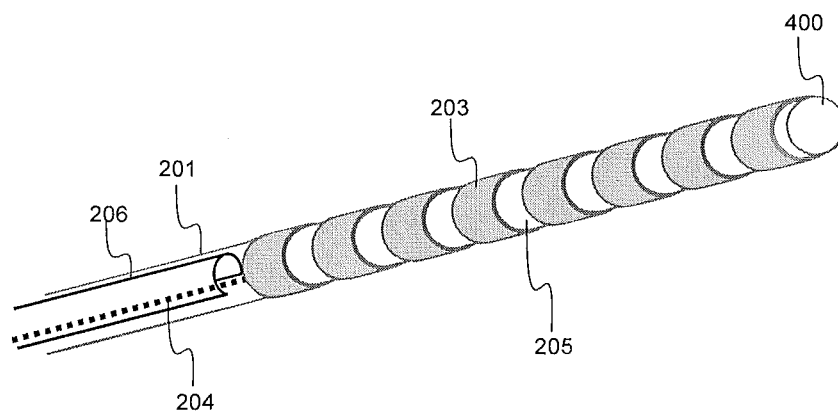


FIG. 15

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IMPLANTABLE LEAD**CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of PCT application PCT/US2012/03220, international filing date Apr. 4, 2012, which claims the benefit of U.S. Provisional Patent Application 61/471,496, filed Apr. 4, 2011, which is hereby incorporated by reference in its entirety

TECHNICAL FIELD

This description is related to implantable neural stimulators.

BACKGROUND

A variety of therapeutic intra-body electrical stimulation techniques can treat neuropathic conditions. These techniques may utilize a subcutaneous battery operated implantable pulse generator (IPG) connected to one or more implantable wired leads. These leads have numerous failure modes, including mechanical dislodgement, impingement of the lead-extension tubing, infection, and uncomfortable irritation from the IPG and extension tubing. Various types of spinal cord stimulation (SCS) leads have been used to provide therapeutic pain relief. These lead configurations often include cylindrical percutaneous leads and paddle lead form factors. Cylindrical percutaneous leads typically have diameters in the range of 1.3 mm and contain a number of circular electrodes used for effectiveness testing during a trial implant period, and in many cases for the permanent implantation. Paddle leads, however, contain electrodes with a greater surface area directionally targeted for control over the excitation of the nerve bundles and may require surgical laminotomy.

SUMMARY

Some embodiments provide an implantable neural stimulator wireless lead. The wireless lead includes: an enclosure; the enclosure housing; a) one or more electrodes configured to apply one or more electrical pulses to a neural tissue; b) a first antenna configured to receive, from a second antenna through electrical radiative coupling, an input signal containing electrical energy, the second antenna being physically separate from the implantable neural stimulator lead; c) one or more circuits electrically connected to the first antenna, the circuits configured to create the one or more electrical pulses suitable for stimulation of the neural tissue using the electrical energy contained in the input signal, and supply the one or more electrical pulses to the one or more electrodes, wherein the enclosure is shaped and arranged for delivery into a subject's body through an introducer or a needle.

Embodiments may include one or more features. For example, a portion of the enclosure may leave the electrodes in a non-direct contact with the neural tissue after the lead has been delivered into the subject's body. The enclosure can be semi-cylindrical in shape and the electrodes may include at least one directional electrode that directs a current path associated with the one or more electrical pulses to a direction that is substantially perpendicular to the neural tissue. The electrodes may include a semi-cylindrical array of electrodes. The electrodes may be made of at least one of: platinum, platinum-iridium, gallium-nitride, titanium-nitride, iridium-oxide, or combinations thereof. The electrodes can include two to sixteen electrodes, each having a longitudinal length between 1.0 and 6.0 mm and a width between 0.4 and 3.0 mm.

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The electrodes are spaced between 1 mm to 6 mm apart and have a combined surface area of between 0.8 mm² to 60.00 mm².

The lead may be a paddle-style lead. Specifically, the lead can be a paddle lead with a height between 1.3 mm and 2.0 mm, and a width between 2.0 mm and 4.0 mm. The lead can be shaped concavely to secure a lateral position on the neural tissue after the lead has been delivered into the subject's body. The lateral position may be with regard to a dorsal aspect of the subject's spinal cord. For example, the lead has a concave profile between 1.0 mm and 1.5 mm, and a concave edge between 0.2 mm and 0.3 mm.

The lead can be delivered into an epidural space of a subject's body. The delivery can be through a needle, such as, for example, a tuohy needle, no larger than gauge 14. The lead may be delivered to treat a neural tissue associated with the spinal column.

The enclosure can further house a lumen to operate a navigating stylet during delivery of the enclosure. The enclosure may further include a distal tip. The distal tip can be rounded with a length of between 0.5 mm and 2.0 mm. The distal tip can also be pointed with a length of between 2.0 and 6.0 mm. The enclosure may have an external coating of bio-compatible polymer, the polymer includes at least one of: polymethylmethacrylate (PMMA), polydimethylsiloxane (PDMS), parylene, polyurethane, polytetrafluoroethylene (PTFE), or polycarbonate. The enclosure may further have an external coating of silicone elastomer. The enclosure can further house antenna coupling contacts, the antenna contacts being electrically connected to the antennas and the circuit and configured to couple the antenna with the surrounding tissue. The antenna coupling contacts can include two to eight antenna-coupling pairs. The antenna coupling contacts may be located proximal, relative to the electrodes, in the enclosure. The antenna coupling contacts can each have a longitudinal length of between 1.0 mm and 6.0 mm, and a width of between 1.0 mm to 2.5 mm. The antenna coupling contacts can be spaced between 30 mm and 80 mm apart. At least one of the antennas can be constructed as a conductive trace contained on one of the circuits. At least one of the antennas can be fabricated as a conductive wire connected to one of the circuits. The circuits can be flexible circuits. The flexible circuits are capable of undergoing a bend radius of under 0.5 mm. The flexible circuits can be placed proximal, relative to the electrodes, in the enclosure. The flexible circuits can include a waveform conditioning circuit.

Some embodiments provide a method of treating neurological pain. The method includes: providing an implantable neural stimulator lead including an enclosure that houses: one or more electrodes; a first antenna configured to receive, from a second antenna and through electrical radiative coupling, an input signal containing electrical energy, the second antenna being physically separate from the implantable neural stimulator lead; one or more flexible circuits electrically connected to the first antenna, the flexible circuits configured to: create the one or more electrical pulses suitable to be applied at the electrodes using the electrical energy contained in the input signal; and supply the one or more electrical pulses to the one or more electrodes, and implanting the neural stimulator lead into a subject's body through an introducer or a needle.

Embodiments may include one or more of the following features. For example, a portion of the enclosure may leave the electrodes in a non-direct contact with a neural tissue after the lead has been implanted into the subject's body. The electrodes can include at least one directional electrode that confines a current path associated with the one or more elec-

trical pulses in a direction substantially perpendicular to the neural tissue. The needle can be a tuohy needle no larger than gauge 14.

DESCRIPTION OF DRAWINGS

FIG. 1 illustrates two wireless paddle leads being implanted through an introducer into the epidural space.

FIG. 2 illustrates a wireless paddle lead being implanted through an introducer into a human body.

FIG. 3 illustrates a wireless paddle lead in place against the dura of the spinal cord.

FIG. 4A illustrates an example of an introducer.

FIG. 4B shows a cross-sectional view of the introducer illustrated in FIG. 4A.

FIG. 5A illustrates another example of an introducer.

FIG. 5B shows a cross-sectional view of the introducer illustrated in FIG. 5A.

FIG. 6A illustrates the distal tip of a wireless paddle lead.

FIG. 6B shows cross-sectional views of the distal ends of three embodiments of a wireless paddle lead.

FIGS. 7A and 7B respectively illustrate the dorsal and ventral sides of an embodiment of a wireless paddle lead.

FIG. 7C illustrates the ventral side of another embodiment of the wireless paddle lead.

FIG. 8 illustrates an embodiment of a cylindrical and a semi-cylindrical wireless lead being placed in the epidural space using a needle.

FIG. 9 illustrates an example of a cylindrical or semi-cylindrical wireless lead being implanted in the epidural space using a needle.

FIG. 10 illustrates a cylindrical or semi-cylindrical wireless lead placed against the dura in the spinal column.

FIG. 11A-11C illustrate cross-sectional views of a semi-cylindrical lead, a cylindrical lead, and a paddle lead, respectively, while those leads are placed against the dura.

FIGS. 12A-12B illustrate perspective and profile views, respectively, of an embodiment of a wireless semi-cylindrical lead.

FIG. 13A-13C variously illustrate the electronic components included in two embodiments of the wireless lead.

FIG. 14A-14B illustrate a cross-sectional view of a fully cylindrical wireless lead or a semi-cylindrical wireless lead.

FIG. 14C illustrates a cross-sectional view towards the distal end of a semi-cylindrical wireless lead.

FIG. 15 illustrates an embodiment of a cylindrical wireless lead.

DETAILED DESCRIPTION

Spinal cord stimulation may treat chronic neuropathic pain, especially low back pain and radiculopathy, vascular insufficiency in the feet or hands, angina, and more. In various implementations, a neural stimulation system can send electrical stimulation to targeted nerve tissue with neither cables nor inductive coupling to power the passive implanted stimulator. This can be used to treat pain or a variety of other modalities. The targeted nerve tissues may be, for example, in the spinal column including the spinothalamic tracts, dorsal horn, dorsal root ganglia, dorsal roots, dorsal column fibers, and peripheral nerves bundles leaving the dorsal column or brainstem, as well as any cranial nerves, abdominal, thoracic, or trigeminal ganglia nerves, nerve bundles of the cerebral cortex, deep brain and any sensory or motor nerves.

The neural stimulation system can include an implantable lead that includes an enclosure that houses one or more conductive antennas (for example, dipole or patch antennas),

internal circuitry for frequency waveform and electrical energy rectification, and one or more electrode pads allowing for neural stimulation of tissue. The neural stimulation system may receive microwave energy from an external source.

5 The implantable lead may be 1.3 mm diameter or smaller. Particular implementations of the circuitry, antennas and pads are described in PCT Application PCT/US2012/023029, which is incorporated herein by reference.

In various embodiments, the implantable lead is powered wirelessly (and therefore does not require a wired connection) and contains the circuitry necessary to receive the pulse instructions from a source external to the body. For example, various embodiments employ internal dipole (or other) antenna configuration(s) to receive RF power through electrical radiative coupling. This can allow such leads to produce electrical currents capable of stimulating nerve bundles without a physical connection to an implantable pulse generator (IPG) or use of an inductive coil. This can be advantageous relative to designs that employ inductive coils to receive RF power through inductive coupling and then transfer the received power to a large IPG device for recharging, particularly since the large IPG device for recharging can be as large as 100 mm by 70 mm.

Furthermore, the electrical radiative coupling mechanism (for example, a dipole antenna) can be utilized to improve the form factor of a wireless lead and allow for miniature diameters, as small as 30 microns. For example, some implementations of the wireless lead, such as those discussed in association with FIGS. 7-15, can have diameters of less than 1.3 mm, and as small as 500 microns while still providing the same functionality as wired spinal cord stimulation leads.

Electrical radiative coupling also allows for the transmission and reception of energy at greater depths with less degradation in efficiency than inductive coil techniques. This can provide an advantage over devices that employ inductive coupling since the efficiency of such implants is highly dependent on the distance separating the external transmitter coil and the implanted receiver coil.

Various embodiments can also include distinct advantages over wired leads in regards to ease of insertion, cross connections, elimination of extension wires, and no requirement for an implantable pulse generator in order to administer a chronic therapy. Various implementations also may have an associated lower overall cost compared to existing implantable neural modulation systems due to the elimination of the implantable pulse generator, and this may lead to wider adoption of neural modulation therapy for patients as well as reduction in overall cost to the healthcare system.

FIG. 1 illustrates two wireless paddle leads 200 (described in more detail below) being implanted through an extended-width introducer 202 into the epidural space. A lead 200 may be advanced and guided into the epidural space utilizing the extension tubing 201 with a handle for manipulating the lead 200. The introducer 202 has an entry point 100 above lumbar spinal column 103 (shown in FIG. 2). Once the introducer 202 is removed, the wireless paddle lead 200 can be anchored in place subcutaneously at entry point 100. Thereafter, extension tubing 201 may remain implanted and may run from the skin placement to the wireless paddle leads 200.

In some embodiments, the tubing 201 contains a lumen for a stylet (otherwise referred to as an "injector lead wire," a "guide-wire," a "navigation wire," or "a steer wire"), which can be used for placing the lead 200. The stylet may be made of metal and can provide steerability strength during implantation of the wireless paddle lead 200. After the wireless paddle lead 200 has been successfully deployed, the metal stylet may be removed. As will be discussed in association

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with FIG. 7C, this lumen, or other lumens in tubing **201**, can be used to also house electronic circuitry.

FIG. 2 illustrates a wireless paddle lead **200** being placed through an introducer **202** typically in the lumbar region in between the L1 and L2 vertebrae. For example, the introducer **202** may be inserted through a small incision in the skin **105** and in between the vertebrae **103**. In certain other embodiments, multiple wireless paddle leads **200**, wireless cylindrical leads **400** (as will be discussed in association with FIGS. **8-15**) and wireless semi-cylindrical leads **300** (as will be discussed in association with FIGS. **8-15**) can be inserted through the same channel of introducer **202**. Wireless paddle leads **200**, cylindrical leads **400** or semi-cylindrical leads **300** for spinal cord stimulation applications can then be implanted and placed against the dura **104** of the spinal column **102**, as described in association with FIG. 3 below.

In certain embodiments, wireless paddle leads **200**, cylindrical leads **400** or semi-cylindrical leads **300** may be adapted to be located within the epidural space of the spinal column, near or on the dura of the spinal column, in tissue in close proximity to the spinal column, in tissue located near the dorsal horn, dorsal root ganglia, dorsal roots, dorsal column fibers and/or peripheral nerve bundles leaving the dorsal column of the spine.

In certain embodiments, wireless paddle leads **200**, cylindrical leads **400** or semi-cylindrical leads **300** can be adapted to be placed and secured to stimulate nerves leaving the spinal column for the treatment of a variety of conditions, such as, for example, pain, angina, peripheral vascular disease, gastrointestinal disorders. In other embodiments, wireless paddle leads **200** can be adapted to treat other conditions via neural stimulation of nerve bundles emanating from the spine. "Spinal cord tissue" and "nerve bundles emanating from the spine" generally refer to, without limitation, the nerve bundles ranging from spinal column levels C1 to L5, dorsal horn, dorsal root ganglia, dorsal roots, dorsal column fibers and peripheral nerve bundles leaving the dorsal column.

FIG. 3 illustrates a wireless paddle lead **200** in place against the dura **104** of the spinal cord after being implanted into the human body for spinal cord stimulation applications. The small incision at the skin **105** can be stitched with a suture or sterile strip after placement of the anchoring mechanism **106**. Wireless paddle leads shown here may have electrodes that confine the current path in a direction generally perpendicular to the dura, as will be discussed in association with FIG. 11C. This directionality may be desirable to zero in on a target particular tissue and to reduce electrical charges for efficacious stimulation.

FIG. 4A illustrates an example of an introducer **214** that can fit in between two vertebrae without the need for a surgical laminotomy or removal of any bone tissue. The introducer **214** includes a handle **212** for use by the medical staff during the insertion procedure. The width of each handle can be between about 8 mm and about 15 mm. The length of each handle can be between about 10 mm and about 18 mm. The thickness of the handle may be between about 2.5 mm and about 6 mm. The introducer **214** has an inner channel **215** that can house, for example, two wireless paddle leads **200** placed one at a time, sequentially through the same introducer channel. As illustrated, the example wireless paddle lead **200** can have a flat tip.

FIG. 4B shows a cross-sectional view of the introducer illustrated in FIG. 4A. This cross-sectional view may also be known as a profile view.

FIG. 5A illustrates another example introducer **214** that can fit through the vertebrae without the need for a surgical

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laminotomy or removal of any bone tissue. The introducer **214** includes a handle **212** for use by the medical staff during the insertion procedure. The introducer **214** has an inner channel **217** that can house, for example, two slim factor wireless paddle leads **220** placed one on top of the other. The two slim factor wireless paddle leads **220** can be stacked vertically in the inner channel **217** at the same time. As illustrated, the example wireless paddle lead **220** can have a pointed tip **219** that aids in directing the paddle lead through the tight epidural space of a smaller patient. The example wireless paddle lead **220** can also have a flat tip that aids in laying the electrode columns parallel with the spine from a fluoroscopic view or rounded tip that aids in both laying the electrode columns parallel with the spine and in directing the paddle lead through the epidural space.

FIG. 5B shows a cross-sectional view of the introducer illustrated in FIG. 5A. This cross-sectional view may also be known as a profile view.

FIG. 6A illustrates the distal tip of a wireless paddle lead **200**. The wireless paddle lead **200** may include, for example, four electrodes **203** and the spacers between the electrodes. The wireless paddle lead **200** can include between two to sixteen electrodes **203** located on the distal end of the lead (not shown). The distal tip may have a height of between about 1.3 mm and about 2.0 mm, and a width between about 2.0 mm and about 4.0 mm. The electrodes **203** may have a longitudinal length between about 1.0 mm and about 6.0 mm from the distal tip toward the proximal tip and a width of between about 0.4 mm and about 3.0 mm. The total electrode surface area of the lead **200** may be between about 0.8 mm² and about 60.0 mm². The spacing between the electrodes **203** may be between about 1 mm and about 6 mm from distal to proximal.

The various leads described herein may include anywhere from one to sixteen electrodes, any of which can be designated by the programmer as either a cathode or an anode. For example, electrodes **203** can include multiple cathodes coupled to the targeted tissue as well as at least one anode. The electrode array can receive electrical stimulation waveform pulses ranging from 0 to 10V peak amplitude at a pulse width reaching up to a maximum of 1 millisecond. The polarity of the electrodes can produce various volume conduction distributions from the cathodes to the anodes to inhibit or excite surrounding nerve tissue, which may include A-δ and/or primary or secondary c-fiber afferents. To minimize electrode impedance, the electrodes may be made of a conductive, corrosion resistant, biocompatible material such as, for example, platinum, platinum-iridium, gallium-nitride, titanium-nitride, or iridium-oxide.

Excluding the electrodes **203**, which are coupled to the surrounding tissue, the remaining portions of the wireless lead embodiments described herein may be insulated from surrounding body tissue partially or totally by an external coating layer of biocompatible dielectric material with a low dielectric constant. Materials with rigidity similar to that of tissue can be used to reduce the risk of migration and the development of fibrous scar tissue. Such fibrous scar tissue can increase electrode-tissue impedance. If the electrode-tissue impedance can be kept low, less energy may be consumed to achieve stimulation of the targeted tissues.

In certain embodiments, the wireless paddle lead **200** can have a rounded tip **211** at the distal end. Rounded tip **211** can be a non-conductive tip. Rounded tip **211** can have a length of between 0.5 mm and 2.0 mm, and a smooth finish for navigating the lead through the epidural space.

In certain embodiments, the wireless paddle lead **200** can have a pointed tip **219** at the distal end. Pointed tip **219** can be

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a non-conductive tip. Pointed tip **219** can have a length of between about 2.0 mm and about 6.0 mm. Pointed tip **219** can enhance the steering capability when the wireless paddle **200** is being deployed.

FIG. 6B shows the cross-sectional views of the distal end of three embodiments of a wireless paddle lead. For example, in certain embodiments, the wireless paddle lead **200** may be a slim factor wireless paddle lead **220**. As illustrated in FIG. 6B, the slim factor wireless paddle lead **220** can be thinner than a regular wireless paddle lead **221**. For example, slim-factor wireless paddle lead may be between about 1.0 mm and about 1.3 mm in height, which can allow multiple slim-factor wireless paddle leads to be implanted simultaneously or sequentially through an introducer **214**. For example, in certain embodiments, wireless paddle leads **200** may be a slim-factor concave wireless paddle lead **207** having a concave profile of between about 1.0 mm and 1.5 mm, concave edges of about 0.2 mm by about 0.3 mm. The concave profile may refer to the height of the slim-factor concave wireless paddle lead **207**. The concave edge may refer to the dimension of the concave shape corner the slim-factor concave wireless paddle lead **207**. The slim factor concave wireless paddle lead **207** may be placed as close as possible to the dorsal spinal column.

In certain embodiments, at least one additional wireless lead may be placed in parallel or offset with the initial wireless lead. In some embodiments, the wireless leads may be activated sequentially. In other embodiments, wireless leads can be activated simultaneously.

FIGS. 7A and 7B respectively illustrate the dorsal and ventral sides of an implementation of a wireless paddle lead **200**. For example, electrodes **203** and between two to eight antenna coupling contacts **222** may be placed on different sides of the wireless paddle lead **200**. As discussed in association with FIG. 6A, two to sixteen electrodes **203** can be located on the distal end and embedded into the electrically insulative material **205** of the wireless lead **200**.

For example, antenna **208** may be coupled to tissue through the antenna coupling contacts **222** located on the ventral side of the wireless paddle lead **200**. The antenna can be, for example, a dipole antenna. Some embodiments may have only one dipole antenna, other embodiments may have multiple antennas of any given length. For example, without limitation, some embodiments may have between two and ten dipole antennas, while other embodiments can have more than ten dipole antennas or more than twenty dipole antennas. In some embodiments, a dipole antenna can range from about 100 microns to about 10 cm in length. In other embodiments, an antenna can consist of any linear dipole configuration ranging from about 20 microns to about 3 mm in thickness. The antenna **208** may also be a folded dipole antenna instead of straight dipole antenna.

Antenna **208** may be configured to receive RF energy from exterior antennas. RF wave propagation energy is divided into two regions, the radiative region and the reactive region. The radiative region is within $2D^2/\lambda$ and the radiated power varies with distance from the antenna. For a short dipole antenna, the reactive component is approximately $\lambda/2\pi$. The induced field for antennas placed in biological tissue is a function of body geometry, tissue properties, and the exposure conditions. The efficiency of the RF waveform inside a lossy media, such as body tissue, is attenuated by the tissue as it propagates. To increase the power efficiency of a small antenna in lossy matter, the dipole antenna configuration can be optimized at high frequencies to minimize losses, such as, for example, from about 800 MHz to 5.8 GHz or greater.

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The antenna coupling contacts **222** in certain embodiments may have a longitudinal length between about 1.0 mm and about 6.0 mm from the distal tip toward the proximal tip and a width of between about 1.0 mm to about 2.5 mm. The spacing between the antenna coupling contacts **222** may be between about 30 mm and about 80 mm. The antenna coupling contracts **222** may improve the efficiency of the radiative coupling between internal antenna **208** and the antenna(s) (not depicted) located externally to the body. The antenna coupling contracts **222** may be made of noncorrosive metals, such as, for example, platinum, platinum-iridium, gallium-nitride, titanium-nitride, or iridium-oxide.

Antenna coupling contacts **222** may be connected by conducting wires **210** to the antenna(s) **208** and the waveform conditioning circuitry **209**. Waveform conditioning circuitry **209** may include, for example electronic components such as, for example diodes, resistors and capacitors. Waveform conditioning circuitry **209** can use the incoming energy to provide a stimulation waveform to the electrodes for excitation of nerve tissue. In some embodiments, frequencies from about 800 MHz to about 5.8 GHz may be received by the implanted antenna **208**. The stimulating waveform released into the tissue from electrodes **203** is rectified to provide waveforms at lower frequencies, e.g., at typically from about 5 Hz to about 1000 Hz.

Waveform conditioning circuitry **209** is configured to rectify the waveform signal received by implanted antenna **208**. Waveform conditioning circuitry **209** may also have charge balance microelectronics to prevent the corrosion of the electrodes. To minimize reflection of the energy back from the electrodes into the circuitry, waveform-conditioning circuitry **209** may include isolation circuits to block high frequency signals.

FIG. 7C illustrates the ventral side of another embodiment of a wireless paddle lead **200**, in which the implanted antenna **208** is separated from the distal end **205** of wireless paddle lead **200**. In some embodiments, the implanted antenna **208** may be placed remotely from the distal end **205** of the wireless paddle lead **200** and inside a lumen in extension tubing **201** within the lead body. In some embodiments, the implanted antenna **208** may be the extension line of one of the antenna coupling contacts **304**. In some embodiments, antenna coupling contacts **304** may be located proximal to the electrodes **203**. Antennas **208** may be further connected to the waveform conditioning circuitry **209** via shielded wiring **210**. The waveform conditioning circuitry **209** may be directly wired to the electrodes **203** (located on the ventral side).

In some embodiments, the wireless leads described herein may have multiple layers. These layers can include, without limitation, encasing material close to the electrodes with a biocompatible compound that elicits minimal scar tissue formation. In addition, layers may include polymers such as, without limitation, polymethylmethacrylate (PMMA), polydimethylsiloxane (PDMS), parylene, polyurethane, polytetrafluoroethylene (PTFE), or polycarbonate. Another layer of a material that may be included contains a small relative permeability and low conductivity located above the antennas **208** to allow for optimal coupling with an exterior antenna (not depicted). Yet another layer can comprise a coating of a silicone elastomer to assist in preventing migration of the wireless lead to the surrounding tissue.

FIGS. 8 and 9 illustrates an example of a wireless cylindrical lead **400** or a wireless semi-cylindrical lead **300** being implanted in the epidural space using needles **301**. Cylindrical wireless leads may also be referred to as circumferential leads, while semi-cylindrical wireless leads may also be referred to as semi-circumferential or semi-elliptical wireless

leads. Wireless cylindrical leads **400** or wireless semi-cylindrical leads **300** can be introduced into the body through needle **301**. The needle **301** may be a tuohy needle, 14-Gauge, or smaller (for example, 22 Gauge). Alternatively, the wireless leads **300** and **400** may be introduced into the epidural space through an introducer **202** (see, for example, FIG. 1). Introducers **202** or needle **301** may be inserted through the outer skin of the body through a small incision in the skin **105** and in between the vertebrae **103** at no more than a 45-degree angle, lateral to the spinous processes off the midline, and placed against the dura **104** of the spinal column **102** to lie perpendicularly to the spinal cord. The wireless leads **300** or **400** can contain extension tubings **201** that terminate just under the entry point **100** of the skin. The wireless lead may be guided upwards in the epidural space according to the angle of introducer or needle insertion. After the wireless lead has been placed, a subcutaneous anchor is used to stop vertical and horizontal migration of the wireless lead.

FIG. 10 illustrates embodiments of a cylindrical wireless lead **300** or semi-cylindrical wireless lead **400** after being implanted. A cylindrical **300** or semi-cylindrical **400** wireless lead may be placed against the dura **104** of the spinal cord and the small incision at the skin **105** is stitched with a suture or sterile strip after placement of the anchoring mechanism **106**.

FIG. 11A-11C respectively illustrate the cross-sectional views of the placement of a wireless semi-cylindrical lead **300**, a wireless cylindrical lead **400**, and a wireless paddle lead **200** after successful implantation in relation to the dura **104** of the spinal cord **101**.

FIG. 11 A shows the placement of a wireless semi-cylindrical lead **300** relative to the dura **104** of the spinal cord **101**. The wireless semi-cylindrical (also referred to as half-circumferential or half-elliptical) lead **300** may have electrodes that are straight, as depicted in FIG. 12A, or that are concave and half-cylindrical in shape. Semi-cylindrical electrodes can match the shape of the enclosure. The semi-cylindrical shape of the enclosure of lead **300** may help the lead to mechanically conform to the contour of the spinal column **102**. The shape of the enclosure can also assist in targeting the electrical volume conduction inward towards the dura **104**, and avoid radiating energy outwards towards the ligaments, vertebrae and skin (non-excitabile tissue). More generally, the conducting field generated by the electrodes is uni-directional in nature because the conducting field culminates mainly in the enclosure and electrode faces are pointed in one direction. By removing the unnecessary emission from over 270 degrees of a cylindrical electrode (see, for example, in FIGS. 14B and 15) radiating towards non-excitabile tissue, the semi-cylindrical wireless lead **300** can reduce the amount of energy required for a successful stimulation. Therefore, the benefits of the example semi-cylindrical wireless lead **300** may include the directional delivery of stimulation energy as confined by the shape of the electrode.

FIG. 11B shows the placement of a wireless cylindrical lead **400** relative to the dura **104** of the spinal cord **101** after successful implantation. As depicted, the wireless cylindrical lead **400** is placed against dura **104**.

FIG. 11C shows the placement of a wireless paddle lead **200** relative to the dura **104** of the spinal cord **101** after successful implantation. As depicted, the wireless paddle lead **200** is placed against dura **104**. Wireless paddle lead **200** may have electrodes that confine the current path in a direction generally perpendicular to the dura. This directionality may be desirable to zero in on a target particular tissue and to reduce electrical charges for efficacious stimulation.

FIGS. 12A and 12B illustrate perspective and profile views, respectively, of an implementation of a wireless semi-

cylindrical lead **300**. The semi-cylindrical lead **300** can have, in certain embodiments between two to sixteen electrodes **203** at the distal end **205**, each with a diameter typically between about 0.8 mm and about 1.4 mm, and concave ventral aspects with bend radiuses typically between about 0.6 mm and about 3.0 mm. The electrodes **203** may have longitudinal lengths between about 1.0 mm and about 6.0 mm from the distal tip towards the proximal tip with widths typically between about 0.4 mm and about 1.0 mm. The total electrode surface area of the wireless lead **300** is typically between about 0.8 mm² and about 60.0 mm². The spacing between the electrode contacts is typically between about 1.0 mm and about 6.0 mm. The distal tip of the lead body may be a non-conductive tip that is pointed with a length of between about 0.5 mm and about 2.0 mm, and a smooth finish for navigating the lead through the epidural space.

The wireless semi-cylindrical lead **300** may include between two to eight antenna coupling contacts **304**, as illustrated in association with FIG. 7C, that are wired to the implanted antenna(s) **208** and the flexible circuits **206** (as illustrated in association with FIGS. 12 and 13). The antenna coupling contacts **304** may be proximal of the electrodes **203**. The antenna coupling pads **304** may have a longitudinal length of between about 1 mm and about 6 mm from the distal tip to the proximal tip. The spacing between the antenna coupling contacts **304** is typically between 30 mm and 80 mm. In some embodiments, small antenna coupling contacts **303**, to be discussed in association with FIG. 13C, may be used. Antenna coupling contacts **303** may have a diameter between about 0.2 mm and about 0.6 mm.

Embodiments of wireless leads described herein can have a larger surface area directed towards the dura mater than existing percutaneous leads. This increased surface area can lower the tissue to electrode impedance values and can lead to larger currents for stimulation.

FIGS. 13A-13C variously illustrate electronic components included in two different embodiments of the wireless lead, namely, a wireless semi-cylindrical lead **300** and a wireless cylindrical lead **400**.

FIG. 13A shows an example wireless lead (e.g. a wireless semi-cylindrical lead **300** or a wireless cylindrical lead **400**) with extension tubing **201**. The tubing **201** may house electrodes **203**, implanted antenna **208**, waveform conditioning circuitry **209**, and wires **210**. As discussed above in association with FIGS. 7A-7B, the waveform conditioning circuitry **209** can include components for rectifying the received RF energy and for charge balancing the waveform for tissue stimulation.

One or more flexible circuits **206** may be used to carry various parts of the electronic components. For instance, the flexible circuits **206** may include the waveform conditioning circuitry **209** and implantable antenna(s) **208**. The flex circuit may also include portions of the wires **210**, which connect the electronics, such as circuitry **209**, to the electrodes **203**. The flexible circuits **206** may be between about 15 mm and about 90 mm long, and about 0.7 mm and about 2.0 mm wide. The total height of the flexible circuit **206** with the waveform conditioning circuitry **209** may be between about 0.2 mm and about 0.4 mm. The flexible circuit **206**, when placed inside of the cylindrical wireless lead **400** may undergo a bend radius under about 0.5 mm. As illustrated in FIG. 13A, in some embodiments, the flexible circuit **206** may contain a conductive trace to act as an antenna **208**.

FIG. 13B shows another example of a wireless lead (e.g. a wireless semi-cylindrical lead **300** and a wireless cylindrical lead **400**) encapsulated that includes tubing **201**. The tubing houses antenna(s) **208** and the waveform conditioning cir-

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circuitry 209, both of which may be formed on a flex circuit 206 similar to the flex circuit described with respect to FIG. 13A. At least a portion of the wires 210 may be formed on the flex circuit as well. Wires 210 connect, for example, the circuitry 209 to the electrodes (not shown in FIG. 13B). Wires 210 also connect the antenna 208 to tissue exposed ring antenna coupling contacts 304. Tissue exposed ring antenna coupling contacts 304 can be circumferential rings with outer diameter between about 0.8 mm and about 1.4 mm, and longitudinal lengths between about 0.5 mm and about 6.0 mm.

FIG. 13C shows yet another example wireless lead (e.g. a wireless semi-cylindrical lead 300 and a wireless cylindrical lead 400) with extension tubing 201. The extension tubing 201 houses antenna(s) 208 and the waveform conditioning circuitry 209, both of which may be formed on a flex circuit 206 similar to the flex circuit described with respect to FIG. 13A. At least a portion of the wires 210 may be formed on the flex circuit as well. Wires 210 connect, for example, the circuitry 209 to the electrodes (not shown in FIG. 13C). Wires 210 also connect the antenna 208 to tissue exposed small antenna coupling contacts 303. Tissue exposed small antenna coupling contacts 303 may be made of a conductive cylindrical piece of metal of diameter between about 0.2 mm and about 0.6 mm and thickness of between about 0.2 mm and about 0.6 mm. Tissue exposed small antenna coupling contacts 303 may contact tissue and can be embedded into the electrically insulative material 205.

FIG. 14A illustrates a cross-sectional view of an embodiment of a fully cylindrical wireless lead 400 or a semi-cylindrical wireless lead 300 at a position proximal to the distal tip. The embodiment shown is a multi-lumen extrusion 305 having a center lumen 204 and multiple orbital lumens 306 (for example, one to ten or more). The multi-lumen extrusion 305 may be proximal to the single-lumen extrusion 307, shown in the right graph, on one wireless lead (for example, a fully cylindrical wireless lead 400 or a semi-cylindrical wireless lead 300). The multi-lumen extrusion 305 may act as backbone for guiding the conducting wires 210, housed in side lumens 306, and a stylet (as discussed in association with FIG. 1) placed through the center lumen 204. The multi-lumen plastic extrusion 305 can be made up of between one to ten or more orbital lumens 306, each with inner diameters of between about 0.1 mm and about 0.6 mm. The multi-lumen plastic extrusion 305 may have an outer diameter of between about 0.8 mm and about 1.4 mm. In certain embodiments, the multi-lumen extrusion 305 may be ablated (i.e., heated to be deformed) to a final outer diameter of between about 0.6 mm and about 0.9 mm which allows the extrusion 305 to connect male to female into a single lumen extrusion 307, as shown in the right graph. A navigation stylet may be placed inside the inner lumen 204 to guide the wireless lead into the epidural space. The inner lumen 204 maintains a clear channel without obstruction and may be fused with the single lumen extrusion 307 at the interconnection between extrusions 305 and 307 and after the above-mentioned ablation.

FIG. 14B illustrates a cross-sectional view of another embodiment of a fully cylindrical wireless lead 400 or a semi-cylindrical wireless lead 300 at a position proximal to the distal tip. This embodiment is a single-lumen extrusion 307, which may have inner diameter of between about 0.3 mm and about 1.4 mm. The single lumen extrusion 307 may be pulled around the outside of, for example, the wireless semi-cylindrical lead 300 and heat formed to match an outer diameter of between about 0.8 mm and about 1.4 mm. The single lumen extrusion 307 can leave sufficient empty space for the flexible circuit 206 to be encapsulated inside. The inner lumen 204 may be offset by a distance indicated by 308

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inside the single lumen 307 to provide a gap space for the flexible circuit 206. Conducting wires 210 from the side lumens 306 may connect to terminal features (not depicted) on the flexible circuit 206. The gap space inside the single-lumen extrusion 307 between the flexible circuit 206 and inner lumen 204 may be back-filled with a biocompatible polymer to give added rigidity for protecting the flexible circuit components 206 and conducting wires 210.

FIG. 14C illustrates a cross-sectional view towards the distal end of a semi-cylindrical wireless lead 300. For a semi-cylindrical wireless lead 300, the concave multi-lumen extrusion 309 may house the conducting wires 210 running from the flex circuit 206 to the electrodes 203. The concave shape of multi-lumen extrusion 309 may allow semi-cylindrical wireless lead 300 to conform to the curvature of the spinal cord. The bend radius of the concave dorsal aspect is between about 0.6 mm and about 3.0 mm. The concave multi-lumen extrusion 309 may contain between one and ten or more orbital lumens 306 acting as channels for conducting wires and a central lumen 204 for the stylet. The lumens 204 and 306 may have inner diameters of between 0.1 mm and 0.6 mm. The orbital lumens 306 may be drilled into from the dorsal side during manufacturing to create channels to connect the conducting wires 210 to the electrodes 203.

FIG. 15 illustrates an example of a fully circumferential wireless lead. The cylindrical wireless lead 400 may have between two and sixteen cylindrical electrodes 203 on its distal end with a diameter between about 0.8 mm and about 1.4 mm for epidural spinal cord stimulation applications. The electrodes 203 may have a longitudinal length of between about 1.0 mm and about 6.0 mm from the distal tip toward the proximal tip. The spacing between the electrode contacts may be between about 1.0 mm and about 6.0 mm. The total electrode surface area of the cylindrical wireless lead body 400 may be between about 1.6 mm² and about 60.0 mm². The distal tip of the cylindrical wireless lead body 400 may be a non-conductive tip that is rounded with a length of between about 0.5 mm and about 1.0 mm, with a smooth finish for navigating the lead through the epidural space. Between two to eight tissue exposed ring antenna coupling contacts 304 may be proximal to the electrodes 203. The tissue exposed circular antenna coupling contacts 304 may have a longitudinal length of between about 1.0 mm and about 6.0 mm from the distal tip toward the proximal tip. The spacing between the tissue-exposed circular antenna coupling contacts 304 may be between about 30 mm and about 80 mm. In certain embodiments, tissue exposed small antenna coupling contacts 303 with a diameter between about 0.2 mm and about 0.6 mm may be used in lieu of the illustrated tissue exposed small antenna coupling contacts 303. Extension tubing 201, as discussed in association with FIGS. 1, 7C, 8 and 9, can provide an enclosure that houses, for example, flex circuitry 206. Flex circuitry 206 has been discussed in association with FIGS. 13A to 13C. Extension tubing 201 may include a center lumen 204. As discussed in association with FIG. 14A, a stylet can be placed through center lumen 204 to provide guidance during implantation of lead 400 into, for example, through a lumen in to a human body.

Various implementations of the technology may allow placement of wireless lead in the epidural space, between the dura mater and arachnoid membranes, or subdurally in the intrathecal space, where significant reactions and scarring would be minimized. Insertion in any of these locations may be done by injecting the device from a smaller gauge needle (e.g., 14 to 22-gauge needle or out of a cannula steered to the proper position by a removable stylet). In some implementations, once in position, no further skin incisions or placement

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of extensions, receivers or implanted pulse generators are needed. Various implementations of the wireless neural modulation system may have significant advantages due to the small size and lack of extension wires for transfer of energy, allowing placement with minimal trauma and long term effective therapy in places where larger implantable devices could cause more scar tissue and tissue reactions that may affect efficacy and safety.

A number of implementations have been described. Nevertheless, it will be understood that various modifications may be made. Accordingly, other implementations are within the scope of the following claims.

What is claimed is:

1. An implantable neural stimulator for modulating neural tissue in a patient, the implantable neural stimulator comprising:

an enclosure shaped and configured for delivery into the patient's body through an introducer or needle;
one or more electrodes housed within the enclosure and configured to apply one or more electrical impulses to neural tissue;

a first antenna housed within the enclosure and configured to receive, wirelessly from a second antenna through electrical radiative coupling, an input signal containing electrical energy, the second antenna being physically separate from the implantable neural stimulator; and
a circuit coupled to the first antenna and the electrodes and configured to generate the electrical impulses suitable for modulation of neural tissue solely using the electrical energy contained in the input signal received wirelessly from the second antenna and to supply the electrical impulses to the one or more electrodes.

2. The implantable neural stimulator of claim 1 wherein the enclosure comprises a fixed length for the electrodes and the circuit of no greater than 14 cm and an additional portion that can be adjusted to any length a portion to space the electrodes from the neural tissue after the implantable neural stimulator has been delivered into the patient's body.

3. The implantable neural stimulator of claim 1 wherein the enclosure comprises a cylindrical or semi-cylindrical shape and the electrodes are directionally configured to direct a current associated with the electrical impulses in a direction that is substantially perpendicular to the neural tissue.

4. The implantable neural stimulator of claim 3 wherein the electrodes comprise a cylindrical or semi-cylindrical array of electrodes.

5. The implantable neural stimulator of claim 1 wherein the neural tissue is associated with the spinal column.

6. The implantable neural stimulator of claim 1 wherein the electrodes comprise two to sixteen electrodes, each having a longitudinal length of about 1.0 to 6.0 mm and a width of about 0.4 to 3.0 mm.

7. The implantable neural stimulator of claim 6 wherein the electrodes are spaced between about 1 mm to 6 mm apart and have a combined surface area of between about 0.8 mm² to 60.00 mm².

8. The implantable neural stimulator of claim 1 wherein the lead comprises a paddle-styled lead having a concave shape configured to secure a lateral position on the neural tissue after the lead has been delivered into the patient's body.

9. The implantable neural stimulator of claim 1 wherein the enclosure has a height of about 1.3 mm to 2.0 mm and a width of about 2.0 mm to 4.0 mm.

10. The implantable neural stimulator of claim 8 wherein the enclosure has a concave profile between about 1.0 mm to 1.5 mm and a concave edge of about 0.2 mm to 0.3 mm.

11. The implantable neural stimulator of claim 8 wherein the lateral position is with regard to a dorsal aspect of a spinal cord of the patient.

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12. The implantable neural stimulator of claim 1 wherein the enclosure is sized and shaped for delivery into an epidural space of the patient's body.

13. The implantable neural stimulator of claim 1 wherein the enclosure is sized and shaped for delivery through a tuohy need having a diameter no larger than gauge 14.

14. The implantable neural stimulator of claim 1 wherein the enclosure further comprises a lumen configured to receive a navigating stylet for delivery of the implantable lead into the patient's body.

15. The implantable neural stimulator of claim 1 wherein the enclosure comprises a rounded distal tip with a length of between about 0.5 mm to 2.0 mm.

16. The implantable neural stimulator of claim 1 wherein the enclosure comprises a pointed distal tip having a length of between about 2.0 to 6.0 mm.

17. The implantable neural stimulator of claim 1 further comprising a plurality of antenna coupling contacts housed within the enclosure and electrically coupled to the antenna and the circuits, wherein the antenna coupling contacts are configured to electrically couple the antenna with tissue surrounding the enclosure.

18. The implantable neural stimulator of claim 17 wherein the antenna coupling contacts comprise 2 to 8 antenna coupling pairs located proximal to the electrode within the enclosure.

19. The implantable neural stimulator of claim 17 wherein the antenna coupling contacts each have a longitudinal length of about 1.0 mm to 6.0 mm and a width of about 1.0 mm to 2.5 mm.

20. The implantable neural stimulator of claim 17 wherein the antenna coupling contacts are spaced between about 30 and 80 mm apart.

21. The implantable neural stimulator of claim 1 wherein the circuits are flexible circuits capable of undergoing a bend radius of under 0.5 mm.

22. The implantable neural stimulator of claim 21 wherein the flexible circuits each comprise a waveform conditioning circuit configured to provide a stimulation waveform to the electrode.

23. A method for modulating a neural tissue in a patient comprising:

implanting one or more electrodes of an implantable neural stimulator at a target site adjacent to or near the neural tissue; and

wireless delivering, through radiative coupling and from a location exterior to the patient's body, an input signal containing electrical energy to the target site where the implantable neural stimulator is implanted such that one or more electrical impulses are generated solely from the electrical energy contained in the input signal wireless delivered through radiative coupling from the exterior location; and wherein the generated electrical impulses are applied through the electrodes to the neural tissue.

24. The method of claim 23 wherein implanting the electrodes includes advancing the one or more electrodes through an introducer.

25. The method of claim 24 wherein the introducer is a needle.

26. The method of claim 23 further comprising spacing the electrodes from the neural tissue.

27. The method of claim 23 wherein the electrical impulses are applied in a direction substantially perpendicular to the neural tissue.

28. The method of claim 25 wherein the needle is a tuohy needle having a size of no larger than gauge 14.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 9,220,897 B2
APPLICATION NO. : 14/045764
DATED : December 29, 2015
INVENTOR(S) : Laura Tyler Perryman, Patrick Larson and Chad Andresen

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page, column 1 (Inventors), line 2, delete "Scottsdaale," and insert -- Scottsdale, --, therefor.

Title Page, column 1 (Related U.S. Application Data), line 2, delete "PCT/US2012/003220"
and insert -- PCT/US2012/032200 --, therefor.

In the Specification

In column 1, lines 6-7, delete "PCT/US2012/03220" and insert -- PCT/US2012/032200 --, therefor.

In the Claims


In claim 1, column 13, line 28, delete "soley" and insert -- solely --, therefor.

In claim 13, column 14, line 6, delete "tuohy need" and insert -- tuohy needle --, therefor.

In claim 23, column 14, line 46 (approx.), delete "wireless" and insert -- wirelessly --, therefor.

In claim 23, column 14, line 46 (approx.), delete "form" and insert -- from --, therefor.

Signed and Sealed this
Sixteenth Day of August, 2016



Michelle K. Lee
Director of the United States Patent and Trademark Office